

Fact Sheet for Pregnant Women: Understanding Results from the **LightMix® Zika rRT-PCR Test**

August 26, 2016

Dear Madam:

You are being given this Fact Sheet because your blood has been tested for evidence of Zika virus infection. This testing was done because your health care provider believes you may have been exposed to the virus. The test used on your sample is called the **LightMix® Zika rRT-PCR Test**, which is a laboratory test designed to help detect Zika virus infection in humans.

This Fact Sheet contains information to help you understand the risks and benefits of using the **LightMix® Zika rRT-PCR Test**. You may want to discuss with your health care provider the benefits and risks described in this Fact Sheet and any additional questions you may have.

What is Zika virus infection?

Zika virus infection is caused by the Zika virus, which is most often spread to people through mosquito bites. A woman infected with Zika virus during pregnancy can pass the virus to her developing baby. Zika virus can also be passed by infected individuals to their partner during sex. Since 2015, a large number of people infected with Zika virus have been reported in many South and Central American, Caribbean countries, and Puerto Rico.

Most people who are infected with Zika virus do not have any symptoms. Those that do, usually have mild illness with symptoms that may include fever, joint pain, rash, or redness of the eyes. These symptoms often resolve on their own within a week.

Infection with Zika virus during pregnancy can cause microcephaly (where the baby's head is smaller than expected, a sign of incomplete brain development) and other severe brain defects in babies. However, detection of Zika virus infection in the mother does not mean there is definite harm to the developing baby. Some women who had Zika virus infection during pregnancy have delivered apparently healthy babies. Women who are infected with Zika virus while pregnant should be monitored more closely by their health care providers throughout their pregnancy.

There have also been reports of a possible link between Zika virus infection and an illness that can cause temporary paralysis (Guillain-Barré syndrome).

What is the **LightMix® Zika rRT-PCR Test**?

The **LightMix® Zika rRT-PCR Test** is a laboratory test designed to detect Zika virus. The U.S. Food and Drug Administration (FDA) has not cleared or approved this test. No FDA-cleared or approved tests exist that can tell whether you have Zika virus infection. However, FDA has authorized the use of this test under an Emergency Use Authorization (EUA).

Why was my sample tested using the *LightMix® Zika rRT-PCR Test*?

Your blood sample was tested because you have symptoms of Zika virus infection and because you live in or have traveled recently to a place where Zika virus infection is known to occur, and/or because you have another possible exposure to Zika virus. The sample collected from you was tested using the *LightMix® Zika rRT-PCR Test* to help find out whether you may be infected with Zika virus. The test results, along with other information, could help your health care provider make decisions about how to take care of you and better monitor your pregnancy.

What are the known and potential risks and benefits of the *LightMix® Zika rRT-PCR Test*?

Besides possible discomfort and other complications that can happen when your sample is collected, there is a risk that the test result will be incorrect (see next paragraphs for more information). The benefit of having this test is that the results of this test, along with other information, can help your health care provider make decisions about how to take care of you and your developing baby.

If this test is positive for Zika, does it mean that I have a Zika virus infection?

If you have a positive test result, it is very likely that you have a Zika virus infection. There is a very small chance that this test can give a positive result that is wrong; this is called a “false positive” result. If your result from this test is positive, your health care provider or health department will work with you to help you understand the steps you should take to care for yourself. They will also work closely with you to monitor the health and development of your baby. Information about steps to take if you are diagnosed with Zika virus infection is available at <http://www.cdc.gov/zika/index.html>.

If this test is positive for Zika virus, does it mean that my child will have a birth defect?

No, not necessarily. While evidence shows that Zika virus infection during pregnancy is a cause of birth defects and other poor pregnancy outcomes, not all Zika virus infections result in these pregnancy problems. At this time, we do not know how often babies will have microcephaly or other problems if a woman is infected with Zika virus while she is pregnant. A positive test result for Zika virus infection during pregnancy signals to your doctor or other health care provider to watch your pregnancy more closely, meaning he or she might do more ultrasounds or other tests to check the growth and development of your fetus and check for any signs of Zika virus infection.

If this test is negative, does it mean that I do not have Zika virus infection?

A negative test result for the *LightMix® Zika rRT-PCR Test* means that Zika virus was not found in your sample. A negative result for a sample collected less than a week after the start of illness usually means that Zika virus did not cause your recent illness.

It is possible for this test to give a negative result that is incorrect (false negative) in some people with Zika virus infection. Most people with Zika virus infection have virus in their blood for up to a week following the start of illness. A negative result that is incorrect can happen if your body fights a Zika virus infection faster than most other people do. It can also happen if your illness/symptoms were very mild and started earlier than the date you first

noticed them. In these cases, the virus may already be gone from your body before the sample is taken for testing.

If your result for the **LightMix® Zika rRT-PCR Test** is negative, you should ask your health care provider or health department if additional testing may be needed. It is important that you work with your health care provider or health department to help you understand the next steps you should take. Your health care provider will work with you to continue to monitor your health and the health of your baby.

What is an Emergency Use Authorization (EUA)?

An EUA is a tool that FDA can use to allow the use of certain medical products for certain emergencies based on scientific data. The U.S. Secretary of Health and Human Services (HHS) has declared that circumstances exist to allow the emergency use of authorized diagnostic tests for Zika virus infection, such as the **LightMix® Zika rRT-PCR Test**, under an EUA.

At this time, there are no FDA approved/cleared alternative tests available that detect Zika virus. FDA has authorized the emergency use of the **LightMix® Zika rRT-PCR Test** to test for the presence of Zika virus in blood specimens. Use of this test is authorized only for the duration of the threat of the emergency, unless it is terminated or revoked by FDA sooner.

How can I learn more?

Information about Zika virus infection is available at the CDC website:

<http://www.cdc.gov/zika/index.html>.

Any significant new findings that negatively impact the performance of the test and that are observed during the course of the emergency use of the **LightMix® Zika rRT-PCR Test** will be made available at lifescience.roche.com.

Please also contact your health care provider if you have any questions.